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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,969	07/21/2005	Tomoharu Suga	44342.024000	2010
7590 GERARD F DIEBNER DREIER LLP 499 PARK AVENUE NEW YORK, NY 10022				
04/11/2008				
EXAMINER				
AHMED, HASAN SYED				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
04/11/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/542,969

## Applicant(s)

SUGA ET AL.

## Examiner

HASAN S. AHMED

## Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of applicants' amendment and remarks, which were filed on 7 January 2008.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Mizumoto, et. al. (U.S. Patent No. 5,576,014).

Mizumoto, et. al. disclose an intraorally rapidly disintegrating tablet (see col. 1, lines 9-28).

The disclosed tablet is the instant tablet as claimed:

- the active ingredient mixed with a sugar of instant claim 6 (see col. 12, lines 24-26);
- the core granule coated with a pharmaceutical disintegrating agent of instant claims 6 and 7 (see col. 7, lines 19-46; col. 13, lines 39-43);
- the active ingredient of instant claims 6 and 7 (see col. 12, lines 23-26);
- the “substantially complete” covering of instant claims 6 and 7 (i.e. the high moldability saccharide coating (see col. 13, lines 5-7) mixed with disintegrating agents (see col. 13, lines 36-41 and lines 58-65);

- the disintegrating agent of instant claims 2 and 8 (*see* col. 13, line 40);
- the sugar of instant claim 3 (*see* col. 7, lines 19 and 20);
- the average particle diameter of instant claims 4 and 9 (*see* col. 7, lines 50 and 51); and
- the tablet thickness of instant claims 5 and 10 (*see* col. 5, line 37).

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed 7 January 2008 have been fully considered and are not persuasive.

1. Applicants list a series of embodiments from Mizumoto, then argue, "[a]ll of these products clearly and succinctly differ from applicants' product which comprises a core substantially completely covered with a disintegrating agent. See remarks, page 5.

Examiner respectfully disagrees. As claimed by applicants, Mizumoto discloses a core comprising a mixture of an active ingredient and a sugar (*see, e.g.* col. 7, lines 24-26; col. 12, lines 24-26; and col. 13, lines 3-7). This core is covered substantially completely with a disintegrating agent (*i.e.* the high moldability saccharide coating (*see* col. 13, lines 5-7) mixed with disintegrating agents (*see* col. 13, lines 36-41 and lines 58-65).

2. Applicants argue that, "...there is no suggestion of substantially completely covering a core in a non-aqueous state with a disintegrant." See remarks, page 6.

As applicants have explained in the remarks, the terms "substantially completely" are not explicitly disclosed in the instant specification, rather, they are implicitly derived

from the teachings of the disclosure. Thus, applicants do not explicitly define "substantially completely" in the instant specification. Examiner respectfully submits that the Mizumoto granule is coated in a manner similar to that disclosed in the instant specification, thus the Mizumoto reference reads on the instant application, as claimed.

Instant examples 1-12 do not disclose a coating of pure disintegrating agent. Rather the granules are granulated in a fluid bed granulation dryer with a solution of purified water and a sugar (e.g. lactose) or a sugar and a binder (e.g. hydroxypropyl cellulose). The disintegrating agent is then added to this aqueous solution, when 1/3 of the solution remains.

Likewise, Mizumoto discloses adding a disintegrating agent to an aqueous solution of a sugar (e.g. a high moldability saccharide) in a granulating machine (see col. 13, lines 3-7 and 58-65). The mixture of high moldability saccharide with disintegrating agent will inherently "substantially completely" coat the core in the granulating machine. As such, Mizumoto reads on the instant application, as claimed and disclosed.

3. Applicants argue that, "...one skilled in the art would not add a disintegrating agent to the coating solution of Mizumoto because it would defeat the purpose of using a disintegrating agent. The disintegrating agent would absorb water from the coating solution and thus cease to function as a disintegrating agent." See remarks, page 6.

The instant specification discloses a coating comprising a mixture of water, a binding agent, a sugar, and a disintegrating agent (see examples 1-12). Mizumoto similarly discloses a coating comprising a mixture of water, a binding agent, a sugar,

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and a disintegrating agent (*see* col. 13, lines 3-7, 36-43, and 58-65). Applicants are not claiming any particular concentration of disintegrating agent, or any particular ratio of disintegrating agent to water.

The disintegrating agents are the same as those instantly claimed, i.e. potato starch, corn starch, and carboxymethylcellulose calcium (*see* col. 13, lines 40-41). These agents are referred to as “disintegrating agents” as opposed to “fillers” or “excipients”, thus the plain language of the disclosure indicates that said agents are intended to facilitate disintegration of the granule when exposed to the buccal cavity.

Mizumoto states that, “[t]he preparation of the present invention may contain various additive agents generally used in the production of tablets so long as they do not spoil the effects of the present invention.” *See* col. 13, lines 32-38. The effects of the Mizumoto invention, as stated throughout the reference, is “quick disintegration and dissolution in the buccal cavity.” *See* abstract. As such, examiner respectfully submits that the Mizumoto invention is consistent with the instant disclosure. The addition of a disintegrating agent to the Mizumoto invention facilitates quick disintegration and dissolution in the buccal cavity. Thus Mizumoto is using the same ingredients as the instant application for the same purpose as the instant disclosure.

\* \* \* \* \*

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

★

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1618

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1618